

K012715

AUG - 1 2003

## 510K Summary of Safety & Effectiveness

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Submitter: Hygia Health Services, Inc.  
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Contact: Mrs. Tracy Wood Comas  
Chief Operating Officer  
Phone: (205) 314-3920  
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Date: August 1, 2003

Trade or  
Proprietary Name: Hygia Health Services Reprocessed D-25 and N-25 Nellcor  
Oximeters

Common Name: Pulse Oximeter sensor, oxygen transducer

Classification: 21CFR 870-2700 - Oximeter  
DQA

Equivalent Device: Corresponding Mallinckrodt, Inc., Nellcor Oximeters legally  
marketed under various 510(k) premarket notifications.

Device Description: The Hygia Health Services Oximeters are non-invasive probes  
used to provide continuous SpO<sub>2</sub> monitoring and pulse rate. The  
probes contain a dual wavelength light emitting diode (LED), and  
an optical photodiode sensor which are housed in a pad which  
attaches to the patient using adhesive material. The LED emits red  
and infrared light in alternate pulses, governed by the Oximeter  
instrument. The photodiode sensor responds to the light and  
generates a current that is interpreted by the Oximeter instrument.  
The Oximeter instrument interprets the different amounts of each  
light type (red and infrared) from the output of the photodiode and  
interprets the information and displays a reading. The sensor  
operates without any type of tissue penetration, electrical contact,  
or heat transfer to the patient. The sensors use optical means to  
determine the light absorption of functional arterial hemoglobin.

## 510K Summary of Safety & Effectiveness (cont'd)

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Indications for

Use:

The sensor is indicated for use as a non-invasive method to provide continuous SpO<sub>2</sub> monitoring and pulse rate.

Technological

Characteristics:

The predicate device and the Hygia Health Services reprocessed device contain dual wavelength LED and a photodiode. The LED and photodiode are encased in a pad which attaches to the patient using adhesive material. The sensors are connected to a cable and they terminate in a pin connector.

Biocompatibility and performance/functional testing demonstrate that the devices are equivalent and are safe and effective for their intended use.

Testing:

Functional testing, cleaning validation, and biocompatibility testing demonstrates that the reprocessed devices perform as intended and are safe and effective.

Conclusion:

Based on the assessment of functional testing, cleaning validation, and biocompatibility testing performed, Hygia Health Services concludes that the Hygia Health Services reprocessed pulse Oximeter sensors are substantially equivalent to the Mallinckrodt, Inc., Nellcor predicate sensors.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG - 1 2003

Ms. Tracy Comas  
Chief Operating Officer  
Hygia Health Services  
434 Industrial Lane  
Birmingham, AL 35211

Re: K012715

Trade Name: Hygia Health Services Reprocessed Nellcor N-25 and D-25 Oxisensors  
Regulation Number: 21 CFR 870.2700  
Regulation Name: Oximeter  
Regulatory Class: II (Two)  
Product Code: NLF  
Dated: May 2, 2003  
Received: May 5, 2003

Dear Ms. Comas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Patricia Cuccinello" followed by a stylized flourish.

Susan Runner, DDS, MA  
Interim Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications For Use


Applicant: Hygia Health Services, Inc.

510(k) Number: K012715

Device Name: Hygia Health Services Reprocessed D-25 and N-25 Nellcor Oximeters

### Indications For Use:

The Hygia Health Services Reprocessed Nellcor Oximeter is used as a non-invasive method to provide continuous SpO2 monitoring and pulse rate.

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices  
510(k) Number: K012715

X PRESCRIPTION DEVICE